

Embracing LEAN strategy to deliver patient-critical expanded access





When patients are not eligible to enroll on a clinical trial but would likely benefit from access to the investigational drug for treatment purposes outside of the study, expanded access is sometimes an appropriate course of action.

Expanded access or compassionate use of investigational drugs provides a lifeline to certain patients, improving their quality of life or extending life expectancy. Yet it can also present supply and demand challenges and increase pressure on manufacturing operations to deliver vital drugs, outside of normal protocols and against a ticking clock.

This was the case for one small, clinical stage biopharmaceutical company committed to developing treatments for a group of rare yet progressive and, ultimately fatal diseases, which affect around 250,000 patients worldwide.



The challenge - clinical site unable to supply patient due to blinding protocol

During phase I of a blinded trial, a patient diagnosed with the disease was identified as a compassionate use case. With no current FDA approved treatments on the market, there was no therapeutic alternative available for this patient, who was suffering with wide ranging and debilitating symptoms.

Time was of the essence. The trial's investigational drug had the potential to halt the progression of the disease, which was already well established. The patient needed the drug as quickly as possible but there were several challenges standing in the way.

As the wallet packaging was blinded, the drug supply at the clinical site couldn't be provided to the patient without compromising the study's blinding protocol. The patient urgently required a three-month supply of the sponsor's drug.

Add to this the strict regulatory requirements surrounding compassionate use cases and it's clear to see how the pressure was mounting for this sponsor to support a very sick patient in need of vital treatment.

Solution - adopting LEAN best practice

Determined to provide the patient with access to the sponsor's drug within a quick turnaround time, Almac harnessed its internal experts in project management, distribution, labelling, production, operations and logistics before collaborating with the sponsor to agree the best, and fastest, course of action.

A LEAN strategy was agreed upon that would best facilitate the quick turnaround time needed.

Initial drug supply was pulled from in-process, unlabeled material. Meanwhile, internal experts across multiple disciplines worked together with the sponsor to utilize the comprehensive change controls and drastically shorten the standard timelines associated with packaging and labelling the drug product.

The Almac results - LEAN processes deliver when it matters most

By adopting a LEAN strategy to label bottles held in inventory and design secondary packaging, and thanks to the strong collaboration with internal teams and the sponsor organization, the clinical need was formalized, the

drug order logged within the IRT system, and packaging and labelling activity was initiated.

As a result, a three-month supply of the drug was shipped to the patient within seven business days. This represents a 75% reduction in the time usually associated with fulfilling this type of demand, when utilizing standard processes.

With this patient-centric LEAN strategy, Almac experts were able to reduce packaging design processes from ten days to three days and labelling processes from five days to two days.

Through a 'one team' approach and utilizing LEAN methodology, the patient received a drug that offered their only hope of halting the progression of a potentially fatal disease. Following compassionate use treatment, the patient was successfully enrolled onto the sponsor's Open Label Extension study, where they will continue to receive this vital therapeutic drug. More than this, the patient will play a small yet significant role in helping to develop a best-in-class breakthrough medicine that will cater for the currently unmet needs of hundreds of thousands of patients worldwide.

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